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EXAMINER
KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 02/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/992,107	Applicant(s) Hope
	Examiner Gollamudi S. Kishore, Ph.D	Art Unit 1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-22* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 U.S.C. § 112

1. **The following is a quotation of the first paragraph of 35 U.S.C. 112:**

> **The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.**

2. Claims 1-3, 7-9 and 13-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for liposomes made of phospholipids, does not reasonably provide enablement for generic liposomes. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

As is well known in the art, liposomes can be made with most of the non-phospholipid amphipathic compounds. Instant invention is drawn to treating atherosclerosis using a phospholipid composition wherein the phospholipids have the ability to remove the cholesterol plaques. The specification neither provides a rationale or examples to show that even non-phospholipid vesicles behave the same way. Broad claims must have broad basis of support in the specification. In the absence such support, claims must be drawn to liposomes made of specific phospholipids disclosed as having the intended function.

Also, the specification lacks adequate support for the broadly used term 'apoproteins' in claim 2.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> **The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

4. Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

On line 1 of claim 1 applicants' recite 'composition consisting essentially of'. However, on line 3 of the claim applicants recite a negative limitation 'liposomes are not bound to a drug'. From this limitation, it is unclear whether applicants' intent is to convey that the liposomes contain a drug in the interior. Since the claim recites consisting essentially of, if the drug is included, then the claim should recite this requirement.

Claim 2 is inconsistent with claim 1 limitation that the liposomes are not bound to a drug. Apoproteins can be considered as drugs since they are involved in cholesterol removal.

'Comprising' in claim 4 is inconsistent with 'consisting essentially of' in claim 1. Similar is the case with claims 6, 10,12 21 and 22.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-7 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,139,871. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant generic liposomes include the liposomes formed from phospholipids claimed in the claims of said patent.

7. Claims 8-22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 of U.S. Patent No. 6,312,719. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant generic liposomes include the liposomes formed from phospholipids claimed in the claims of said patent.

Claim Rejections - 35 U.S.C. § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> **A person shall be entitled to a patent unless --**
>
> **(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.**

9. Claims 1, 3 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Liu (BBA, 1990).

Liu discloses liposomes of instant sizes(note the abstract, Materials and Methods, and results).

10. Claims 1, 3-13, 18 and 21-22 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 470 437.

EP teaches unilamellar liposomes having an average diameter of 100 nm containing phosphatidylcholine for the treatment of atherosclerosis (note pages 10, 11, 15 and 16 of the English translation).

Claim Rejections - 35 U.S.C. § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention**

was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP cited above by itself or in view of Williams 1984.

EP does not provide specific examples for the treatment of atherosclerosis. It would however, been obvious to an artisan to use liposomes for the treatment of atherosclerosis based on the teachings of EP. EP does not specifically state that the phosphatidylcholine used should be from eggs. EP does not also specifically teach instant protocol and mode of administration. In the absence of showing unexpected results, these parameters are deemed to be obvious parameters manipulated by an artisan to obtain the best possible results. One of ordinary skill in the art would be motivated to administer the liposomes of EP by an intravenous injection, with the expectation of obtaining similar results since the reference of Williams et al teaches the administration of similar liposomes for the treatment of the same disease (note the entire article of Williams, pages 417, 418, 422, 424 and 425 in particular).

13. Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams (1984 or 1986) in view of Liu.

Williams (1984) teaches the administration of liposomes for treating atherosclerosis, but does not teach the sizes (pages 418-423). This parameter however, if different from instant invention, is deemed to be an obvious parameter manipulated by an artisan to obtain the best possible results. Instant liposome sizes are also deemed to be obvious to one

of ordinary skill in the art in view of Liu's teachings that SUVs of about 120 nm have greater circulation time.

Williams (1986) disclose a method of removal of serum cholesterol using liposomes (note the abstract, Introduction, Materials and Methods and Discussion, last paragraph in particular). Although on page 185, col. 1, Williams discloses the use of 0.22 mm filter, he does not specifically teach instant sizes.

Liu teaches that small liposomes (<200 nm) remain in circulation for a longer periods (note page 348, col. 2, Results on page 350, col. 1).

To prepare liposomes of Williams (1984 or 1986) having sizes within the claimed range would have been obvious to one of ordinary skill in the art since liposomes of those sizes are able to survive the circulation system for longer periods (and hence their enhanced cholesterol removal effect) as taught by Liu. The protocol of administration is deemed to be an obvious parameter manipulated by an artisan.

14. Claims 5 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over (EP cited above by itself or in view of Williams 1984) or (Williams (1984 or 1986) in view of Liu) as set forth above, further in view of Barenholz (4,812,314).

The primary references do not teach instant phospholipids. Such a use however, would have been obvious to one of ordinary skill in the art in view of Barenholz's teachings of the general ability of phospholipids to remove cholesterol through a variety of

physiological transfer proteins (note col. 2, line 41 through col. 3, line 25). An artisan would expect at least similar removal of cholesterol by other phospholipids.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.

Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

February 7, 2002